

# **EXHIBIT A**

Jerry G. Blaivas, M.D.

1 IN THE UNITED STATES DISTRICT COURT  
2 FOR THE SOUTHERN DISTRICT OF  
WEST VIRGINIA AT CHARLESTON

4 IN RE: ETHICON, INC., :Master File No.  
PELVIC REPAIR SYSTEM :2:12-MD-0237  
5 PRODUCTS LIABILITY :  
LITIGATION :MDL No. 2327

7 THIS DOCUMENT RELATES TO :JOSEPH R. GOODWIN  
THE CASES LISTED BELOW :U.S. DISTRICT JUDGE

9 Mullins, et al. v. Ethicon, Inc., et al.  
2:12-cv-02952  
10 Sprout, et al. v. Ethicon, Inc., et al.  
2:12-cv-07924  
11 Iquinto v. Ethicon, Inc., et al.  
2:12-cv-09765  
12 Daniel, et al. v. Ethicon, Inc., et al.  
2:13-cv-02565  
13 Dillon, et al. v. Ethicon, Inc., et al.  
2:13-cv-02919  
14 Webb, et al. v. Ethicon, Inc., et al.  
2:13-cv-04517  
15 Martinez v. Ethicon, Inc., et al.  
2:13-cv-04730  
16 McIntyre, et al. v. Ethicon, Inc., et al.  
2:13-cv-07283  
17 Oxley v. Ethicon, Inc., et al. 2:13-cv-10150  
Atkins, et al. v. Ethicon, Inc., et al.  
2:13-cv-11022  
18 Garcia v. Ethicon, Inc., et al. 2:13-cv-14355  
Lowe v. Ethicon, Inc., et al. 2:13-cv-14718  
19 Dameron, et al. v. Ethicon, Inc., et al.  
2:13-cv-14799

21 SEPTEMBER 17, 2015  
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1 CAPTION CONTINUED:  
2  
3 Vanbuskirk, et al. v. Ethicon, Inc., et al.  
2:13-cv-16183  
4 Mullens, et al. v. Ethicon, Inc., et al.  
2:13-cv-16564  
5 Shears, et al. v. Ethicon, Inc., et al.  
2:13-cv-17012  
6 Javins, et al. v. Ethicon, Inc., et al.  
2:13-cv-18479  
7 Barr, et al. v. Ethicon, Inc., et al.  
2:13-cv-22606  
8 Lambert v. Ethicon, Inc., et al.  
2:13-cv-24393  
9 Cook v. Ethicon, Inc., et al. 2:13-cv-29260  
Stevens v. Ethicon, Inc., et al.  
10 2:13-cv-29918  
Harmon v. Ethicon, Inc., et al. 2:13-cv-31818  
11 Snodgrass v. Ethicon, Inc., et al.  
2:13-cv-31881  
12 Miller v. Ethicon, Inc., et al. 2:13-cv-32627  
Matney, et al. v. Ethicon, Inc., et al.  
13 2:14-cv-09195  
Jones, et al. v. Ethicon, Inc., et al.  
14 2:14-cv-09517  
Humbert v. Ethicon, Inc., et al.  
15 2:14-cv-10640  
Gillum, et al. v. Ethicon, Inc., et al.  
16 2:14-cv-12756  
Whisner, et al. v. Ethicon, Inc., et al.  
17 2:14-cv-13023  
Tomblin v. Ethicon, Inc., et al.  
18 2:14-cv-14664  
Schepleng v. Ethicon, Inc., et al.  
19 2:14-cv-16061  
Tyler, et al. v. Ethicon, Inc., et al.  
20 2:14-cv-19110  
Kelly, et al. v. Ethicon, Inc., et al.  
21 2:14-cv-22079  
Lundell v. Ethicon, Inc., et al.  
22 2:14-cv-24911  
Cheshire, et al. v. Ethicon, Inc., et al.  
23 2:14-cv-24  
24

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<p>1 Q. And when you mention current      2 studies on the autologous fascial sling,      3 what current studies are you referring      4 to?</p> <p>5 A. I mean, there was just a      6 study by -- I don't remember who the      7 primary author was, the first author was.      8 But there was a study by Roger      9 Dmochowski's group. There's a study by      10 Eric Rovner comparing synthetic slings      11 to -- synthetic slings to autologous      12 fascia slings.</p> <p>13 And my recollection is that      14 the findings were comparable. But I      15 would really -- I would need to see those      16 papers to answer your question. I mean,      17 to answer with certainty.</p> <p>18 Q. You didn't cite to Dr.      19 Dmochowski's paper or Eric Rovner's paper      20 in your expert report, correct?</p> <p>21 A. No.</p> <p>22 Q. I'm not correct?</p> <p>23 A. Correct, yes.</p> <p>24 Q. Oh, thank you.</p>	<p>1 years, studies --      2 A. Yes.      3 Q. -- of midurethral slings      4 effectiveness.      5 Do you see that?      6 A. Yes, I do.      7 Q. So there are 11 studies      8 mentioned here in Table 1, correct?      9 A. Correct.      10 Q. Were there more than 11      11 studies found that fulfilled these      12 criteria of a follow-up duration of five      13 years or more but for some reason did not      14 make it into Table 1?</p> <p>15 MS. FITZPATRICK: Objection.</p> <p>16 THE WITNESS: I honestly      17 don't know. I don't think so, but      18 I don't know for sure. I could      19 find out.</p> <p>20 BY MR. SNELL:</p> <p>21 Q. The sixth paper down is a      22 paper by Serati, 2013.</p> <p>23 A. Yes.</p> <p>24 Q. It looks like that involved</p>
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<p>1 A. I thought you said you      2 didn't. Oh, okay.</p> <p>3 Q. Let's just -- we have a      4 double negative and that's my bad.</p> <p>5 How about we make it this      6 way: Did you cite to either Dr.      7 Dmochowski's paper or Dr. Rovner's paper      8 in your expert report?</p> <p>9 A. I did not.</p> <p>10 Q. Thank you.</p> <p>11 MR. SNELL: Let's take a      12 break.</p> <p>13 - - -</p> <p>14 (Whereupon, a brief recess      15 was taken.)</p> <p>16 - - -</p> <p>17 BY MR. SNELL:</p> <p>18 Q. In your paper that was      19 published this year on midurethral      20 slings, we were discussing the long-term      21 studies that were found, correct?</p> <p>22 A. Yes.</p> <p>23 Q. Table 1 says, Long-term      24 follow-up duration of more than five</p>	<p>1 transobturator slings.      2 Do you see that?      3 A. Correct.      4 Q. And that had a duration of      5 follow up of 60 months?      6 A. Yes.      7 Q. Were you aware that there's      8 a paper by Serati on the TVT retropubic      9 device with a follow up of greater than      10 ten years using very similar methodology      11 to this paper that you cite regarding      12 transobturator slings?</p> <p>13 MS. FITZPATRICK: Objection      14 to form.</p> <p>15 THE WITNESS: No.</p> <p>16 BY MR. SNELL:</p> <p>17 Q. That's a paper you've never      18 read?</p> <p>19 MS. FITZPATRICK: Objection      20 to form.</p> <p>21 Can you identify the paper      22 specifically for him?</p> <p>23 MR. SNELL: Yes.</p> <p>24 BY MR. SNELL:</p>

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<p>1 Q. The ten-year plus Serati 2 paper on the TVT retropubic device, is 3 that a study you've read?</p> <p>4 A. No.</p> <p>5 MS. FITZPATRICK: Do you 6 have a copy of it? Or a cite to 7 it or something like that so we 8 have a clear record of what we're 9 talking about?</p> <p>10 MR. SNELL: I'm sure we can 11 get a cite.</p> <p>12 THE WITNESS: Or the year it 13 was published?</p> <p>14 MS. FITZPATRICK: Or a copy 15 of the paper, too.</p> <p>16 MR. SNELL: I'm not going to 17 ask him about something he hasn't 18 read, so --</p> <p>19 MS. FITZPATRICK: I just 20 want to make sure that you're both 21 talking about the same thing. So 22 he needs to see what the paper is 23 and say, yes, I've read it or no, 24 I haven't.</p>	<p>1 BY MR. SNELL: 2 Q. Doctor, I don't have a 3 printout, but I'll show it to you. 4 Tension-free Vaginal Tape for the 5 Treatment of Urodynamic Dynamic Stress 6 Incontinence: Efficacy and Adverse 7 Effects at 10-Year Follow Up, published 8 in the European Urology Journal, Volume 9 61, 2012. 10 Have you read that study? 11 A. Can I see it? 12 MS. FITZPATRICK: Can we get 13 a printout of that? 14 MR. ROSENBLATT: Yes. 15 MS. FITZPATRICK: That would 16 be great. Thanks. 17 BY MR. SNELL: 18 Q. Can I come look over your 19 shoulder, because I don't have a copy 20 either? 21 A. Sure. 22 Do you know why it's doing 23 that? 24 Q. I think the connection is</p>
<p>1 THE WITNESS: Can you repeat 2 that?</p> <p>3 MS. FITZPATRICK: I said I 4 want him to show you the article 5 so you can say yes, I've read it 6 or no, I haven't, instead of just 7 asking.</p> <p>8 BY MR. SNELL:</p> <p>9 Q. In Table 1, there is no 10 ten-year TVT study, we can agree on that, 11 correct, by Serati, at all?</p> <p>12 A. Correct.</p> <p>13 Q. And you don't know whether 14 whoever did the searches came across it 15 and purposely did not put it in there for 16 some reason or another?</p> <p>17 MS. FITZPATRICK: Objection.</p> <p>18 THE WITNESS: It is -- I 19 would think that's highly, highly 20 unlikely that they came across it 21 and didn't include it.</p> <p>22 I mean, I don't know, it 23 might have not met our search 24 criteria. I don't know.</p>	<p>1 very slow. 2 A. Oh, you're getting this off 3 the -- 4 Q. Yes. It's off the Internet. 5 A. This is what I want to see. 6 No, I don't remember seeing 7 that. And I want to just check one thing 8 here. 9 MR. SNELL: Do you have a 10 copy of this paper, Paul? 11 MR. ROSENBLATT: No. I can 12 get one made. 13 MR. SNELL: We'll come back 14 to that, Doctor. 15 THE WITNESS: Okay. 16 BY MR. SNELL: 17 Q. As far as you recall, you 18 don't remember reading that ten-year 19 paper by Serati at all? 20 A. No. Which doesn't mean I 21 haven't seen it. And I may have it -- I 22 may have seen it. 23 Q. If you'd go to Page 4. 24 A. May I just take one second?</p>

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<p>1 Q. Let's go off the record, 2 then. 3 - - - 4 (Whereupon, a discussion off 5 the record occurred.) 6 - - -</p> <p>7 THE WITNESS: In the Nature 8 review article, we originally 9 included the methodology by which 10 we selected and rejected papers 11 and in the -- sorry. 12 I just -- we can go off the 13 record now. They moved it. 14 What I was going to say is 15 that --</p> <p>16 MS. FITZPATRICK: This 17 should be on the record. 18 THE WITNESS: I was looking 19 for the search criteria, and the 20 editors took it out of the method 21 section. And I just realized they 22 put it in a box on the side. So 23 I'd like to refresh my memory and 24 look at it.</p>	<p>1 done and they used terms, TVT 2 tension-free vaginal tape, tension free 3 vaginal sling. 4 Correct? 5 A. Correct. 6 Q. And the search was done, 7 limited to human patients, clinical data, 8 correct? 9 A. Correct. 10 Q. And this review was done in 11 August 2014? 12 A. Correct. 13 Q. And we just looked at the 14 Serati ten-year TVT study, and in the 15 title, it talks about tension-free 16 vaginal tape, correct? 17 A. Correct. 18 Q. And it was published in a 19 well-respected European urology journal 20 in 2012. 21 We saw that, right? 22 A. Correct. 23 Q. And it was in human women 24 with ten years or more duration of</p>	
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<p>1 BY MR. SNELL: 2 Q. You're looking at the last 3 page of -- 4 A. Page 21. 5 Q. Correct. 6 The last page of the paper, 7 before the references? 8 A. Yes. 9 Q. Under the color box that 10 says, Review criteria? 11 A. Yes. 12 We're on the record? 13 Q. Yes. We're on the record. 14 A. Unfortunately, they edited, 15 because of their journal guidelines, to 16 the point where I can't find the 17 information that I need to see whether or 18 not I would have seen that article or 19 rejected it or not. 20 So I will not have an 21 independent recollection of whether I saw 22 it or not. 23 Q. Just so we can agree, 24 though, it says, This says a search was</p>	<p>1 follow-up, correct? 2 A. Well, I haven't seen -- I 3 saw the title. I didn't read the -- look 4 at the paper. But in the title it says 5 ten years, yes. 6 MS. FITZPATRICK: If you're 7 going to ask him questions about 8 the article specifically, can we 9 get a copy? 10 MR. SNELL: I'm going to get 11 a copy. 12 BY MR. SNELL: 13 Q. But as you sit here, you 14 have no idea, then, why that paper did 15 not make it into the table that you 16 reported in your article of long-term 17 five-year studies? 18 A. That's correct. 19 Q. And there very well could be 20 other studies of five-years duration, or 21 more, with the TVT that, for reasons 22 unbeknownst to you, do not show up in 23 that table, correct? 24 MS. FITZPATRICK: Objection.</p>	

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<p>1 Q. Yes.      2 A. Yes, this was Burch. I'm      3 quite certain about that, because I was      4 shocked to see it. But it was so long      5 ago that I read it, I couldn't possibly      6 tell you when.      7 Q. Considering that you      8 included the five-year TTVT-O study by      9 Serati in that table but you didn't      10 include this ten-year TTVT study, as you      11 sit here now, I know I asked you this      12 earlier, but do you know why that was not      13 captured?</p> <p>14 MS. FITZPATRICK: Objection.      15 Asked and answered.</p> <p>16 THE WITNESS: I am going to      17 find out. I don't know why.</p> <p>18 BY MR. SNELL:</p> <p>19 Q. This study is consistent      20 with your review, in particular with      21 regard to the rate of dyspareunia      22 long-term with TTVT, correct?</p> <p>23 MS. FITZPATRICK: Objection.      24 THE WITNESS: A dyspareunia</p>	<p>1 A. Yes.      2 - - -      3 (Whereupon, Exhibit      4 Blaivas-13, Heinonen Paper, was      5 marked for identification.)      6 - - -      7 BY MR. SNELL:      8 Q. I have another one for you.      9 I'm not going to go through all of the      10 ones, but I'm going to give you a couple      11 of them.      12 I've handed you Exhibit 13.      13 This is a paper by Heinonen. This is a      14 10.5 year follow-up with Ethicon TTVT.      15 Do you see that?      16 A. Let me just take a look.      17 Q. Sure. And I think we can be      18 pretty brief about this one.      19 This is a long-term study on      20 TTVT, correct, Doctor?      21 A. Yes.      22 Q. This paper was not      23 identified in that long-term study table      24 either in your review, correct?</p>
<p>1 rate of zero? No. It's not -- we      2 don't have -- not a zero      3 dyspareunia rate. It's no      4 dyspareunia.</p> <p>5 BY MR. SNELL:</p> <p>6 Q. Right. Maybe I messed the      7 question up.</p> <p>8 Actually, this study by      9 Serati, the ten-year follow-up, is      10 actually consistent with what you wrote      11 in the AUA stress incontinence      12 guidelines, correct, with regard to      13 dyspareunia rates?</p> <p>14 A. That's correct, yes. I      15 thought you were referring to our Nature      16 article.</p> <p>17 Q. And this study by Serati,      18 that you didn't include in the Nature      19 article, is inconsistent with what you      20 wrote in your review article, correct?</p> <p>21 A. In what way?</p> <p>22 Q. Because it reports zero      23 dyspareunia and you say there's more,      24 correct?</p>	<p>1 A. That's correct.      2 Q. In this study, there was      3 about 28 percent loss to follow up,      4 correct? 138 of 191 patients were able      5 to be evaluated?      6 A. If you did the math, that      7 looks about right. Okay.      8 Q. They say 72 percent.      9 Do you see that?      10 A. I do.      11 Q. So that's within that range      12 of what's to be expected at ten years,      13 correct?      14 A. Yes.      15 Q. And these authors concluded      16 that the TTVT was effective and safe even      17 after ten years, correct?      18 A. Yes. We've agreed that it's      19 effective.      20 The safe, just give me a      21 moment, I'm checking.      22 Okay.      23 Q. Do you know why you didn't      24 cite to this paper either in your table</p>

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<p>1 of long-term TVT studies?</p> <p>2 A. I do not.</p> <p>3 Q. They reported three --</p> <p>4 strike that.</p> <p>5 They reported three</p> <p>6 patients, 2.3 percent, had late-onset</p> <p>7 adverse events, correct?</p> <p>8 A. Where is that, please?</p> <p>9 Q. It's in the very front.</p> <p>10 A. Okay. I mean, I was looking</p> <p>11 in the methods, and there's nothing in</p> <p>12 the methods that I can see about</p> <p>13 adverse -- about any mechanism to</p> <p>14 follow-up for adverse events. So let me</p> <p>15 just --</p> <p>16 Q. Well, you see, if you look</p> <p>17 under the methods, the fourth paragraph</p> <p>18 above, when they brought these women back</p> <p>19 in for this 10.5 year follow-up visit --</p> <p>20 A. Where are you now?</p> <p>21 Q. Right here. Right above</p> <p>22 results. They did a gynecologic exam, a</p> <p>23 stress test, they reviewed the hospital</p> <p>24 records.</p>	<p>Page 194</p> <p>1 questionnaires -- I know most of these</p> <p>2 questionnaires, most of these</p> <p>3 questionnaires would ask specifically</p> <p>4 about dyspareunia or pelvic pain.</p> <p>5 Q. Did you see that they did</p> <p>6 gynecologic exams?</p> <p>7 A. Yes, but that's not --</p> <p>8 that's not a measure of pain.</p> <p>9 Q. Well, during -- you do</p> <p>10 gynecologic exams, correct?</p> <p>11 A. Yes.</p> <p>12 Q. And you know that when you</p> <p>13 do a gynecologic exam, you can elicit a</p> <p>14 painful response from the patient,</p> <p>15 correct?</p> <p>16 MS. FITZPATRICK: Objection.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. SNELL:</p> <p>19 Q. Do these authors, at 10.5</p> <p>20 years, report that they elicited any type</p> <p>21 of painful response from any patient</p> <p>22 during their gynecologic exam?</p> <p>23 A. I don't see any methodology</p> <p>24 that would ask for that. I mean, the way</p>
<p>1 And it says, This was done</p> <p>2 to acquire information on later</p> <p>3 acquired...adverse events after the TVT</p> <p>4 operation.</p> <p>5 Correct?</p> <p>6 A. Yes, that would account for</p> <p>7 some complications. It would not account</p> <p>8 for the most impactful complication,</p> <p>9 which is chronic pain. You wouldn't,</p> <p>10 likely, go to the hospital for that.</p> <p>11 But I accept the rest of it.</p> <p>12 Q. Well, none of these patients</p> <p>13 reported chronic pain when they were</p> <p>14 assessed at 10.5 years, did they?</p> <p>15 A. I didn't see -- I looked,</p> <p>16 and I'll look again, but I don't see</p> <p>17 anything in the methodology where they</p> <p>18 were asked about that.</p> <p>19 General quality of life and</p> <p>20 the stuff that -- this was all -- so far</p> <p>21 as I can see, was -- all of these were</p> <p>22 questionnaires. I don't see anything</p> <p>23 that wasn't a questionnaire.</p> <p>24 And there are no</p>	<p>Page 195</p> <p>1 all these studies are done, eventually</p> <p>2 this stuff becomes a table, and the table</p> <p>3 is going to be a score and there's going</p> <p>4 to be a score for each of the symptoms.</p> <p>5 And unless there's a score for pain or a</p> <p>6 score for dyspareunia, even if the</p> <p>7 patient had it and even if they told</p> <p>8 someone, there isn't a mechanism that I</p> <p>9 can see in the methods to discover that.</p> <p>10 Q. So the different</p> <p>11 questionnaires, it's your statement that</p> <p>12 none of those questionnaires would have</p> <p>13 assessed pain or the impact of</p> <p>14 incontinence on sexual function?</p> <p>15 A. Even if -- I mean --</p> <p>16 Q. It's a yes-or-no question.</p> <p>17 A. What's that?</p> <p>18 MS. FITZPATRICK: Objection.</p> <p>19 Objection. You can answer it any</p> <p>20 way you need to, to fully,</p> <p>21 completely and truthfully answer</p> <p>22 the question.</p> <p>23 THE WITNESS: Please</p> <p>24 rephrase the question. Not</p>

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<p>1 rephrase, just restate it.      2 BY MR. SNELL:      3 Q. Do any of the questionnaires      4 that they used assess sexual function in      5 any manner?      6 MS. FITZPATRICK: Objection.      7 THE WITNESS: None of the      8 ones that I recognize do. I mean,      9 it's -- none of the ones that I      10 recognize do, is the answer to the      11 question.      12 BY MR. SNELL:      13 Q. This paper was published in      14 the International Journal of Urology.      15 Are you familiar with that      16 journal?      17 A. Yeah. Yes, I am.      18 Q. Is that a good journal?      19 MS. FITZPATRICK: Objection.      20 THE WITNESS: I think      21 it's -- yeah, I think it's an      22 adequate journal.      23 BY MR. SNELL:      24 Q. Is this a good study or a</p>	<p>1 consequence of complications.      2 That was the purpose of --      3 that was the purpose of the      4 review.      5 - - -      6 (Whereupon, Exhibit      7 Blaivas-14, 2014 Laurikainen      8 Article, European Association of      9 Urology, was marked for      10 identification.)      11 - - -      12 BY MR. SNELL:      13 Q. Doctor, I'm handing you a      14 five-year randomized control trial by      15 Laurikainen, published in the European      16 Association of Urology, January 2014.      17 Do you see that?      18 A. I do.      19 Q. This is another study that      20 didn't show up in that table in your      21 review article, correct?      22 A. Yeah, my -- I'm pretty sure      23 that this one is after our -- even though      24 it says 2014, I'm pretty sure this was</p>
<p style="text-align: center;">Page 199</p> <p>1 poor study? How would you characterize      2 this study that wasn't included in the      3 table of your review?      4 A. I would characterize this as      5 a very good study. Both of these are      6 very good studies.      7 Q. Do you have any idea why      8 this wasn't included?      9 A. I do not.      10 Q. Are you going to attempt to      11 try to figure out why these ten-plus year      12 TTV studies were left out of the table      13 and which other ones may have been left      14 out, too?      15 MS. FITZPATRICK: Objection.      16 THE WITNESS: I've already      17 started doing that.      18 But, in context, this review      19 is not about efficacy, it's about      20 complications. So there      21 wouldn't -- this -- neither of      22 these papers, as far as I'm      23 concerned, adds very much to our      24 understanding of the incidence and</p>	<p style="text-align: center;">Page 201</p> <p>1 after our review dates.      2 And this one I have seen,      3 though. This one, I do remember seeing      4 this one before.      5 Q. It's interesting that you      6 say that, because, Doctor, earlier we      7 looked at the review criteria, and it      8 states that the systematic review was      9 done in August 2014, which is, you know,      10 eight months after this was published,      11 correct?      12 A. I was looking, I don't see      13 the actual publication.      14 Q. It says on the left,      15 Published online, January 30, 2014.      16 A. Then I don't have an      17 explanation. I don't know what the exact      18 date of our cutoff was.      19 Q. But the search was done,      20 actually, in August 2014, which is months      21 after this was published?      22 A. Okay.      23 Q. We can agree to that,      24 correct?</p>

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<p style="text-align: right;">Page 322</p> <p>1 need another one, correct?</p> <p>2 A. No. That's what I was</p> <p>3 saying before. I mean, we've seen many</p> <p>4 patients that have had -- had an</p> <p>5 intervention and are okay for a couple of</p> <p>6 years and then need another one.</p> <p>7 I mean, that's my practice.</p> <p>8 And I see that commonly.</p> <p>9 Q. I understand. I understand</p> <p>10 that that can occur.</p> <p>11 But I'm talking about</p> <p>12 probability.</p> <p>13 A. We specifically looked --</p> <p>14 was that a question? You did not ask a</p> <p>15 question yet, I'm sorry.</p> <p>16 Q. My question was focused on</p> <p>17 probability.</p> <p>18 I will give you that</p> <p>19 patients can go back for a second</p> <p>20 reoperation. I'm talking about</p> <p>21 probability and what the actual data</p> <p>22 showed.</p> <p>23 In this study -- let me see,</p> <p>24 I think it's reported in here. For the</p>	<p style="text-align: right;">Page 324</p> <p>1 patient will need just one surgery?</p> <p>2 A. No, that's correct, it's not</p> <p>3 clear to me.</p> <p>4 Q. Is it important to you to</p> <p>5 know whether or not a patient you're</p> <p>6 treating for mesh removal is involved in</p> <p>7 litigation?</p> <p>8 A. No, not really.</p> <p>9 Q. Have you evaluated the</p> <p>10 medical literature with regard to</p> <p>11 potential bias by financial gain to</p> <p>12 patients involved in litigation and how</p> <p>13 they report their symptoms to doctors?</p> <p>14 MS. FITZPATRICK: Objection.</p> <p>15 THE WITNESS: No.</p> <p>16 BY MR. SNELL:</p> <p>17 Q. Are you aware if there is</p> <p>18 literature, though, on that topic?</p> <p>19 A. No.</p> <p>20 Q. Haven't you written in the</p> <p>21 past that patients involved in litigation</p> <p>22 have a financial incentive to make</p> <p>23 claims?</p> <p>24 MS. FITZPATRICK: Objection.</p>
<p style="text-align: right;">Page 323</p> <p>1 sling cohort, less than half had to have</p> <p>2 a second surgery.</p> <p>3 Is that consistent with your</p> <p>4 recollection of this study?</p> <p>5 A. Yes. But the follow-up</p> <p>6 was -- the follow-up for all of these</p> <p>7 things is too short for there to be any</p> <p>8 meaningful conclusion about whether or</p> <p>9 not they needed another operation.</p> <p>10 Q. Well, based on the data,</p> <p>11 though, it was more likely than not that</p> <p>12 one surgery would suffice in this study</p> <p>13 for the sling patients?</p> <p>14 A. I just -- I just said what</p> <p>15 my opinion was.</p> <p>16 Q. In the sling procedure, it</p> <p>17 said 23 percent had more than one</p> <p>18 surgery. So to that -- that, to you,</p> <p>19 does not mean -- 23 percent of the women</p> <p>20 who had these tertiary care center</p> <p>21 treatments had to have more than one</p> <p>22 surgery.</p> <p>23 That does not mean, to you,</p> <p>24 that it's more likely than not that a</p>	<p style="text-align: right;">Page 325</p> <p>1 THE WITNESS: I haven't</p> <p>2 written that, no.</p> <p>3 BY MR. SNELL:</p> <p>4 Q. You haven't?</p> <p>5 In your opinion, does the</p> <p>6 TVT adequately treat stress urinary</p> <p>7 incontinence?</p> <p>8 MS. FITZPATRICK: Objection.</p> <p>9 THE WITNESS: In terms of</p> <p>10 efficacy, yes.</p> <p>11 BY MR. SNELL:</p> <p>12 Q. And in your opinion, I take</p> <p>13 it you believe that the pubovaginal sling</p> <p>14 also adequately treats stress</p> <p>15 incontinence?</p> <p>16 A. Yes.</p> <p>17 Q. Apparently, over lunch, or</p> <p>18 some time, you called someone to try to</p> <p>19 get information about why papers were</p> <p>20 left off of your review?</p> <p>21 A. I did.</p> <p>22 Q. Who did you call?</p> <p>23 A. My previous -- actually, one</p> <p>24 of the authors of the paper, I think it</p>

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<p>1 was Matt Benedon. But he's a previous 2 research coordinator. 3 Q. Where is he at now? 4 A. He's still in New York, but 5 he doesn't work for me anymore. 6 Q. And what did you ask Matt? 7 A. Why those weren't there. 8 Q. What did he say? 9 A. That we used -- if the same 10 author wrote a previous paper using the 11 same cohort of patients, he only included 12 the one with the latest -- our 13 methodology was to only include the one 14 the latest date. 15 So, for example, one of the 16 papers we didn't -- I forgot who the 17 first author was, but the senior author 18 was Nilsson, we did not include the 19 five-year paper, we included the 20 seventeen-year paper. There was a series 21 of papers. 22 So there were three that -- 23 that was one. 24 The Serati, or whatever that</p>	<p>1 A. We may -- let me see the 2 paper. 3 MS. FITZPATRICK: This is my 4 copy of it. I don't know what 5 number it is. 6 BY MR. SNELL: 7 Q. You said one with Nilsson. 8 I think that's the one where Nilsson is 9 on. 10 A. Give me one second. 11 Q. Can I look over your 12 shoulder? I can't find mine in that big 13 stack. 14 Yes, this is Nilsson, okay. 15 A. You're correct about that. 16 But that's the explanation. They thought 17 when the computer -- you know, the way we 18 did it, it pulled it up as the same 19 author, and they thought it was the same 20 cohort. 21 Q. But it's clearly not, 22 correct? 23 A. It's clearly not, correct. 24 Q. And it should have been</p>
<p>1 one was, the 2013 paper was -- the 2 five-year follow-up was published later 3 than the ten-year follow-up, because the 4 ten-year follow-up was just TTVT -- 5 Q. Can I stop you right there? 6 A. Yes. 7 Q. First of all, the cohort of 8 patients in Nilsson's study that's been 9 reported out to 17 years, that I know you 10 cited, is not the same cohort of people 11 in the prospective randomized five-year 12 control trial; you and I know that, 13 right? 14 A. They're different -- no, 15 they are different papers, right. 16 Q. They are different cohorts 17 of patients, right? 18 A. Let me see the paper. Which 19 one are you talking about? 20 Q. I'll take these one by one. 21 The first one you mentioned 22 with Nilsson, that's the Laurikainen 23 five-year RCT. 24 Where is your paper at?</p>	<p>1 included, correct? 2 A. Yes, it should have. 3 Q. And Serati, those are two 4 different cohort of patients because the 5 ten-year study was TTVT patients and the 6 five-year were TTVT-O patients, correct? 7 A. And TTVT. One of them had 8 TTVT and TOT, I thought. 9 Well, let me see the two 10 papers, and we'll see. 11 MS. FITZPATRICK: I've only 12 got one. I think we only have one 13 marked, and I'm not sure what it 14 is. 15 BY MR. SNELL: 16 Q. Do you have it in front of 17 you there, Doctor? 18 A. I must. 19 MS. FITZPATRICK: Is it 20 Number 12? Here. That's the only 21 one we have. We don't have the 22 second one, I don't think, the 23 2013. 24 THE WITNESS: I need to see</p>

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<p>1       the other one, the one that --      2       this is what year? I need to see      3       the one that was printed -- what      4       year is this?      5       This is 2012. We need to      6       see the one from 2014. The same      7       author had a paper in 2014.      8       MS. FITZPATRICK: 2013.      9       THE WITNESS: 2013.</p> <p>10 BY MR. SNELL:</p> <p>11 Q. But that was a group of      12 TTVT-O patients that were only analyzed at      13 five years?</p> <p>14 A. Can I just see it?</p> <p>15 Q. I don't have it, but we have      16 it on the computer here.</p> <p>17 A. Let me see in the table --      18 hold on.</p> <p>19       Let me just see in our      20 table. I'll be able to tell just by      21 looking in the table.</p> <p>22 Q. I think the simple thing is      23 this. I think you should be able to      24 agree with me that a ten-year group of</p>	<p>1       on. This doesn't change the      2       conclusions one bit.</p> <p>3 BY MR. SNELL:</p> <p>4 Q. I thought you said that      5 there is less long-term ten-year data on      6 TTVT?</p> <p>7 A. Including this. I already      8 went through the fact that the      9 methodology to look at the kinds of      10 complications that we saw is not      11 sufficient. It didn't seek it out.</p> <p>12       I mean, it didn't have a      13 way -- I mean, again, I agree that 8      14 percent is a great loss to follow up.      15 But the problem is, it's not so great --      16 it's great for efficacy. But it's not so      17 great looking for complication that      18 occurs in 1 or 2 percent of patients.</p> <p>19       So if only one -- there's      20 only one patient, one or two patients      21 that had that complication, they were      22 more likely to be in the      23 loss-to-follow-up group according to --      24 or -- they were very likely to be, I</p>
<p>1       women who got TTVT implanted is not the      2       same group who had five-year follow-up      3       after a TTVT-O implanted?</p> <p>4       A. Of course. But --</p> <p>5       Q. In your paper, you cited to      6       this five-year TTVT-O paper, and I'll give      7       you that, it's in there, but the ten-year      8       TTVT group was not in there?</p> <p>9       A. Just let me check one thing.</p> <p>10       That's correct. And that      11 was -- that was just an error. But the      12 error was because it was the same author      13 with mesh slings. And our methodology      14 said that if it was -- they mistakenly      15 thought it was the same cohort.</p> <p>16       Q. Clearly, it's important to      17 capture ten-year TTVT studies that are out      18 there in the published literature and      19 journals like European Urology, correct?</p> <p>20       MS. FITZPATRICK: Objection.</p> <p>21       THE WITNESS: Not to -- not      22 in a safety consideration for      23 synthetic sling study that is      24 already -- there's plenty of data</p>	<p>1       couldn't say that they were more likely      2 to be.</p> <p>3       They are at least one-third      4 more likely to be in that group because      5 we know at least one-third of the      6 patients don't go back to their original      7 doctors.</p> <p>8       So that an 8 percent loss to      9 follow up, although extraordinarily      10 commendable for an efficacy study, is not      11 so commendable to look for something that      12 happens 1 or 2 percent of the time.</p> <p>13       Q. The problem with what you      14 just said, though, Doctor, is when you      15 said we know a third of the patients      16 don't go back to their doctors, we know      17 that in Serati, 92 percent of them went      18 back to their doctors, right?</p> <p>19       MS. FITZPATRICK: Objection.</p> <p>20       THE WITNESS: That's right.</p> <p>21       But 8 percent did not.</p> <p>22 BY MR. SNELL:</p> <p>23 Q. But 8 percent and a third is      24 a big difference, isn't it?</p>

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<p>1 MS. FITZPATRICK: Objection.      2 THE WITNESS: Well, no, no.      3 I actually stand by what I said.      4 I don't think I need to say it      5 again.      6 BY MR. SNELL:      7 Q. So in Serati's paper, where      8 only 8 percent didn't go back to the      9 doctor, why are you telling me that we      10 know a third of patients don't go back to      11 their doctor?      12 MS. FITZPATRICK: Objection.      13 Mischaracterizes his testimony.      14 THE WITNESS: The reason I      15 said that is there's a chance that      16 the -- let's say these -- I forget      17 the numbers now, but these were,      18 like, 60 patients or 70 patients.      19 So 60 patients, if one -- we      20 would not expect there to be more      21 than one, say, erosion out of      22 that. That would be -- you know,      23 that would, or urethral      24 obstruction that required -- say</p>	<p>1 BY MR. SNELL:      2 Q. I'm really trying to      3 understand your methodology and your      4 statement there.      5 MS. FITZPATRICK: Objection      6 to the form of the question.      7 THE WITNESS: I'll try to      8 say it again.      9 I didn't say they're more      10 likely to be in that group. I      11 didn't say that they are more      12 likely to be in that group. It's      13 just that I think that -- maybe I      14 did say that. If I did, I      15 misspoke.      16 I said there's a chance that      17 they could be in the group. And      18 since the complications we're      19 talking about are so uncommon,      20 okay, I don't think it's fair to      21 say that if a complication didn't      22 occur in the 92 percent of the      23 patients that were followed up,      24 that, therefore, it never</p>
<p>1 requiring surgery would be 1 or 2      2 percent. Okay.      3 So there only -- in that 8      4 percent, the one patient could      5 have been the one patient who had      6 the complication, and that one      7 patient, it would be more likely      8 that that person would be in the      9 loss-to-follow-up group than in      10 the not loss-to-follow-up group.      11 BY MR. SNELL:      12 Q. How is it that you can say      13 that that one patient is more likely in      14 the loss-to-follow-up group than the 92      15 percent of the patients who did return?      16 MS. FITZPATRICK: Objection.      17 THE WITNESS: I already      18 explained my rationale for that.      19 BY MR. SNELL:      20 Q. I don't understand it.      21 It would seem to me that      22 sheer statistical 92 percent probability      23 that they would come back?      24 MS. FITZPATRICK: Objection.</p>	<p>1 occurred. That's all I'm saying.      2 BY MR. SNELL:      3 Q. Okay. We can agree that in      4 Serati's paper, where 92 percent of the      5 patients did come back and they didn't      6 report any de novo dyspareunia and they      7 did not see any exposure, that's actually      8 a good thing for those patients who came      9 back and were able to be evaluated?      10 A. I'm going to split it      11 between the dyspareunia and the erosion.      12 All the patients were      13 examined, so I'll give you that.      14 But the dyspareunia, if you      15 don't ask about it and you don't know if      16 the patient is sexually active, you can't      17 make a comment about dyspareunia, in my      18 judgment. If they say they have      19 dyspareunia, you can make a comment. If      20 you did not say specifically, do you have      21 sex and does it hurt, I don't think you      22 can say -- you can make a comment.      23 Q. But when the authors report      24 there was no de novo dyspareunia, that</p>
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<p>1 means they asked about it, they assessed      2 it, right?      3       A. If that were the case, it      4 would be in the methods. And if it      5 wasn't -- if they asked about it and did      6 not put it in the methods, then it's      7 their fault for not putting it in the      8 methods. And if they didn't ask about      9 it, then they can't conclude it.      10       And I don't even like      11 talking about this because I think it's      12 very good paper. I don't mean to malign      13 the authors at all. This is an excellent      14 paper, but just not with respect -- they      15 did the best they could with this stuff.      16 But it's not good enough to satisfy me      17 that if the patients don't complain of      18 pain, they don't have it.      19       I haven't -- I made my      20 statement.      21       Q. Regardless, that's a paper      22 that should have been in your review,      23 right?      24       A. Yes.</p>	<p>1 data and we did use it for calculations.      2 It just didn't make -- it just didn't get      3 in that table.      4       Q. So there is much more five      5 year long-term data in the literature      6 than what you put in that table, correct?      7       A. Well, there are three.      8       Q. Three that I showed you      9 today?      10       A. Yes.      11       Q. There could be 12 more?      12       MS. FITZPATRICK: Objection.      13       THE WITNESS: I don't know.      14       But if there are, let's not      15 discuss them today.      16 BY MR. SNELL:      17       Q. Is part of your methodology      18 based on case series?      19       A. Yes.      20       Q. Do you give more weight to      21 case series than randomized control      22 trials or systematic reviews?      23       A. I give weight to anything      24 that documents a complication. I don't</p>
<p>1       Q. And you were about to --      2 were you about to give me some      3 justification for why the other paper      4 didn't show up in there?      5       A. Which one was that?      6       Q. Heinonen, 10.5 years,      7 follow-up, no long --      8       A. Which one?      9       Q. Heinonen, 10.5 years --      10       A. I need to see it.      11       MS. FITZPATRICK: This one.      12 BY MR. SNELL:      13       Q. No late tissue reaction      14 exposure, where they did vaginal      15 examinations with speculum?      16       A. This just missed the table,      17 it's in the paper. This is referenced,      18 it's part of our data. We just -- it      19 didn't get in the table.      20       Q. In your paper, you reported      21 there were only 11.      22       That one obviously should      23 have been in there as well?      24       A. Yeah. But we did use it as</p>	<p>1 give weight to someone that doesn't      2 comment on -- you know, on complications.      3       So most of the studies,      4 many -- I would say -- I could say that      5 most of the studies don't even have      6 anything in their methodology to accrue      7 complications, other than -- than patient      8 reported.      9       So if the patient says --      10 said that it hurt, something hurts, they      11 would accept it. But they don't -- if      12 they don't prompt for it, they don't      13 check for it, I don't give that any      14 credence at all.      15       Q. Nilsson, 17-year paper?      16       A. Yes.      17       Q. Are you critical of the loss      18 to follow up in that paper as being      19 something outside the norm for a 17-year      20 data set or is that within the norm of      21 what you would expect at 17 years?      22       A. Again, the loss to follow      23 up, I think, was acceptable for that      24 period of time. But some of the stuff</p>

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1           IN THE UNITED STATES DISTRICT COURT  
2           FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

3           AT CHARLESTON

4           IN RE: ETHICON, INC., :Master File No.

5           PELVIC REPAIR SYSTEM :2:12-MD-0237

6           PRODUCTS LIABILITY :

7           LITIGATION :MDL No. 2327

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8           THIS DOCUMENT RELATES TO :JOSEPH R. GOODWIN  
9           THE CASES LISTED BELOW :U.S. DISTRICT JUDGE

10          Mullins, et al. V.           2:12-cv-02952  
11          Ethicon, Inc., et al.  
12          Sprout, et al. V.           2:12-cv-07924  
13          Ethicon, Inc., et al.  
14          Iquinto v. Ethicon,        2:12-cv-09765  
15          Inc., et al.  
16          Daniel, et al. V.         2:13-cv-02565  
17          Ethicon, Inc., et al.  
18          Dillon, et al. V.         2:13-cv-02919  
19          Ethicon, Inc., et al.  
20          Webb, et al. V.           2:13-cv-04517  
21          Ethicon, Inc., et al.  
22          Martinez v. Ethicon,      2:13-cv-04730  
23          Inc., et al.  
24          McIntyre, et al. V.      2:13-cv-07283  
25          Ethicon, Inc., et al.  
26          Oxley v. Ethicon,        2:13-cv-10150  
27          Inc., et al.  
28          Atkins, et al. V.        2:13-cv-11022  
29          Ethicon, Inc., et al.  
30          Garcia v. Ethicon,        2:13-cv-14355  
31          Inc., et al.  
32          Lowe v. Ethicon,         2:13-cv-14718  
33          Inc., et al.  
34          Dameron, et al. V.       2:13-cv-14799  
35          Ethicon, Inc., et al.  
36          Vanbuskirk, et al. V.    2:13-cv-16183  
37          Ethicon, Inc., et al.

38           SEPTEMBER 24, 2015

39          CONTINUED DEPOSITION OF JERRY G. BLAIVAS, M.D.

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1	CAPTION CONTINUED:	
2	Mullens, et al. V.	2:13-cv-16564
3	Ethicon, Inc., et al. Shears, et al. V.	2:13-cv-17012
4	Ethicon, Inc., et al. Javins, et al. V.	2:13-cv-18479
5	Ethicon, Inc., et al. Barr, et al. V.	2:13-cv-22606
6	Ethicon, Inc., et al. Lambert v. Ethicon,	2:13-cv-24393
7	Inc., et al. Cook v. Ethicon, Inc.	2:13-cv-29260
8	Stevens v. Ethicon, Inc., et al.	2:13-cv-29918
9	Harmon v. Ethicon, Inc.	2:13-cv-31818
10	Snodgrass v. Ethicon, Inc., et al.	2:13-cv-31881
11	Miller v. Ethicon, Inc.	2:13-cv-32627
12	Matney, et al. V.	2:14-cv-09195
13	Ethicon, Inc., et al. Jones, et al. V.	2:14-cv-09517
14	Ethicon, Inc., et al. Humbert v. Ethicon,	2:14-cv-10640
15	Inc., et al. Gillum, et al. V.	2:14-cv-12756
16	Ethicon, Inc., et al. Whisner, et al. V.	2:14-cv-13023
17	Ethicon, Inc., et al. Tomblin v. Ethicon,	2:14-cv-14664
18	Inc., et al. Schepleng v. Ethicon,	2:14-cv-16061
19	Inc., et al. Tyler, et al. V.	2:14-cv-19110
20	Ethicon, Inc., et al. Kelly, et al. V.	2:14-cv-22079
21	Ethicon, Inc., et al. Lundell v. Ethicon,	2:14-cv-24911
22	Inc., et al. Cheshire, et al. V.	2:14-cv-24999
23	Ethicon, Inc., et al. Burgoyne, et al., V.	2:14-cv-28620
24	Ethicon, Inc., et al. Bennett, et al., V.	2:14-cv-29624

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1                   Continued transcript of JERRY G. BLAIVAS,  
2                   M.D., called for Oral Examination in the  
3                   above-captioned matter, said deposition taken by and  
4                   before SILVIA P. WAGE, a Certified Shorthand  
5                   Reporter, Certified Realtime Reporter, Registered  
6                   Professional Reporter, and Notary Public for the  
7                   States of New Jersey, New York, Pennsylvania and  
8                   Delaware, at the offices of URO CENTER, 445 East  
9                   77th Street, New York, New York, on Thursday,  
10                  September 24, 2015, commencing at 2:48 p.m.

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1 Q. I would not misrepresent some data to 2 you. 3 A. No. 4 Q. Is that okay? 5 A. Yeah, I agree. 6 Q. A P-value of less than .03 is 7 statistically significant, correct? 8 A. Yes. 9 Q. Okay. And there was a significant 10 decline in subjective cure that was seen in the IVS 11 cohort, correct? 12 A. Correct. 13 Q. Vaginal erosions were tracked in the 14 study as well, right? 15 A. Yes. Well, it -- it wasn't tracked. 16 It says that it was defined as -- it doesn't 17 actually say how they determined that. 18 Q. You see they say that vaginal 19 erosions were found in 11.8 percent of women in the 20 IVS group and none in the TVT group, correct? 21 A. Yes. 22 Q. And under the results follow-up, 23 you'll see the median follow-up in this study was 24 78 months, correct?	1 correct? 2 A. Yes. 3 Q. And the IVS mesh is not a Type 1 4 macroporous monofilament polypropylene mesh, 5 correct? 6 A. The which? 7 Q. The IVS mesh is not a Type 1 8 monofilament -- 9 A. No, it's not. 10 (There is a discussion off the record.) 11 A. Excuse me. It's not. It's not. 12 Q. Just so we have a clear record now, 13 the IVS where there was over an 11 percent rate of 14 vaginal exposure seen is not a Type 1 macroporous 15 monofilament polypropylene mesh like TVT retropubic, 16 correct? 17 A. Correct. 18 Q. Alright. And do you have any idea 19 why this paper wasn't cited in your review? 20 MS. FITZPATRICK: Objection. 21 A. I assume it was likely an exclusion 22 criteria based on our very detailed methodology. I 23 don't know. 24 Q. You don't know that as you sit here
1 A. Let me just see. I just want to 2 check one thing out. 3 Yeah, I'm not finding the numbers lost to 4 follow-up. 5 MR. SNELL: [MOTION] Move to strike. 6 Q. You see my question was, Doctor -- 7 and I have very limited time -- the median length of 8 follow-up in the TVT group was 78 months, correct? 9 A. Yes. 10 Q. Alright. And you'll see, actually, 11 all of Page 706, they have a whole section on the 12 treatment of these vaginal erosions. 13 A. Yes. 14 Q. And that flows all the way over to 15 the next page, Table 5, where they identify all the 16 different presenting symptoms in women with vaginal 17 erosions, correct? 18 A. Yes. 19 Q. Including how treatment was necessary 20 or not in the women who had the vaginal erosions, 21 correct? 22 A. Yes. 23 Q. And, just to reiterate, and all of 24 these patients with erosions were in the IVS group,	1 today? 2 A. No. 3 (Deposition Exhibit Blaivas 26, Long-term 4 Results of the Tension-free Vaginal Tape Procedure 5 in an Unselected Group: A 7-year Follow-up Study 6 authored by Andreas Reich, Frauke Kohorst, Rolf 7 Krelenberg and Felix Flock, was marked for 8 identification.) 9 Q. Exhibit 26, you see this is long-term 10 results of the TVT procedure in an unselected group 11 of patients, seven-year follow-up, correct? 12 A. Let me look at it. I mean, I'm 13 seeing this for the first time. 14 Q. Fair enough. Let me ask you this. 15 This is, actually, published in the Journal 16 of Urology, correct? 17 A. Yes. 18 Q. That's a journal you get, right? 19 A. Yes, I get it. 20 Q. Is that the journal to my left here 21 on the bookcase? 22 A. It is. 23 Q. Okay. Fair enough. 24 MR. SNELL: Go off the record.
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